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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Nick N. Nguyen

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03/17/2008

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EXAMINER

CHORBAJI, MONZER R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/728,973	Applicant(s) NGUYEN ET AL.	
	Examiner MONZER R. CHORBAJI	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/09/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This non-final action is in response to the RCE submitted on 10/02/2007

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 9, line 7; Applicant recites the feature "admitting no carrier gas into the vaporizer". The disclosure has no literal basis for this language. Applicant should limit the claim by using the transitional phrase "consisting of".
- Claim Rejections - 35 USC § 102**

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatanaka (EP 0 321 908).

With respect to claim 1, The Hatanaka ('908) reference teaches an apparatus for vaporizing a sterilant (figure 1:1) including the following: an inlet (figure 2:20), an outlet (figure 1:13), a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9) between the inlet (20) and the outlet (13), and a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13).

With respect to claims 2-3 and 6, the Hatanaka ('908) reference teaches the following: a plurality of baffles (figure 2, the unlabeled volume containing baffles 9), the circuitous path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion (figure 2, volume through baffles 9 that the sterilant flows in an opposite direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 4, claim 5 (independently) and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0 321 908).

With respect to claim 4, the Hatanaka ('908) reference discloses an apparatus that includes a portion (figure 2, unlabeled space containing 9), which increases by at least 70% or more when compared with for example, structure 10 in figure 2. Depending on the desired residence time within the apparatus, minimizing or maximizing such a region is well within the scope of the artisan. The Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing

Art Unit: 1797

thereby residence time is based on mixing. Thus, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka ('908) apparatus to provide a section of increased cross-sectional area in order to achieve the desired mixing time.

With respect to claim 5, The Hatanaka ('908) reference teaches an apparatus for vaporizing a sterilant (figure 1, 1) including the following: an inlet (figure 2, 20), an outlet (figure 1, 13), a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9) between the inlet (20) and the outlet (13), and a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13) having an labeled inner orifice space connected to 10. Further, the cross-sectional area of the flow restriction (figure 2, 1, the unlabeled space immediately above the entrance point to 10 has a cross-sectional area) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice. Depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice would have been a matter of routine experimentation. The Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing. The residence time is based on the desired mixing of the gases. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of at least a

portion of the Hatanaka circuitous path and the flow restrictor in order to achieve the desired mixing time.

With respect to claims 7-8, the flow restriction (figure 1, 9A) of the Hatanaka ('908) apparatus is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time (by varying the temperature and pressure through the vessel, one of ordinary skill would be able to vary the residence time in the vessel). The Hatanaka reference recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. In addition, residence time depends on the dimensions of the flow restriction. Thus, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the flow restriction in the Hatanaka apparatus in order to increase residence time of the sterilant and thereby achieve the desired mixing time.

9. Claims 9-12, 14-16 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al (U.S.P.N. 4,744,951) in view of Hatanaka (EP 0 321 908).

With respect to claim 9, the Cummings reference teaches a method for hydrogen peroxide vapor sterilization in a chamber (col.1, lines 12-16) including the following: creating temperature (col.3, lines 61-63) and vacuum pressure (col.3, lines 21-23 and lines 29-30) conditions within the vaporizer to vaporize the sterilant (col.1, lines 32-35), admitting the sterilant in its liquid phase into the vaporizer (col.3, lines 30-32), admitting

Art Unit: 1797

no carrier gas into the vaporizer (the Cummings reference removes any air within the vaporizer and only injects hydrogen peroxide solution into the vaporizer), passing the sterilant in its vapor through a flow restriction (passage 20 in the figure due to its small diameter restricts the flow of the vapor going from the vaporizer 10 to the sterilization chamber 22) and passing the sterilant in its vapor phase out of the vaporizer (col.3, lines 36-46). However, the Cummings reference fails to teach passing the sterilant through a circuitous path.

The Hatanaka ('908) reference teaches passing the sterilant through a circuitous path (in figure 2, the circuitous path is made up of the unlabeled volume containing 14 and baffles 9 as indicated by the arrows). This is done to remove any liquid sterilant entrained within the vapor (see column 2, lines 34-42 and column. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a passing the sterilant through a circuitous path as taught by the Hatanaka ('908) reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from carrying entrained drops out of the vaporizer.

With respect to claims 15-16, the Cummings reference discloses using liquid hydrogen peroxide (col.2, lines 51-53) such that water is a stabilizing compound for the liquid phase of the sterilant.

With respect to claims 10-12 and 14, the Cummings reference fails to teach the following: passing the sterilant past a plurality of baffles, passing the sterilant in a first

Art Unit: 1797

direction through an inner tube positioned concentrically within an outer tube, a second opposite direction between the inner tube and the outer tube, passing the sterilant through at least one portion in which an effective cross-sectional area of the portion increases by at least 89% and having the sterilant make at least two turns each of which are at least 90 degrees.

However, the Hatanaka ('908) reference discloses the following: passing the sterilant past a plurality of baffles (figure 2, the unlabeled volume containing baffles 9), the circuitous path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion (figure 2, volume through baffles 9 that the sterilant flows in an opposite direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a passing the sterilant through a circuitous path as taught by the Hatanaka ('908) reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from carrying entrained drops out of the vaporizer.

With respect to claims 19-20, the Cummings reference fails to teach that the sterilant remains within the vaporizer for at least 17 milliseconds or for at least 26

milliseconds. With respect to claims 19-20, the flow restriction (figure 1, 9A) of the Hatanaka ('908) apparatus is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. The Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. In addition, residence time depends on the dimensions of the flow restriction. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the flow restriction of the Cummings reference in order to increase residence time of the sterilant and thereby achieve the desired mixing time as taught by the Hatanaka reference.

10. Claims 13 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0 321 908) in view of Hatanaka et al (U.S.P.N. 4,797,255).

With respect to claims 13 and 17, the Hatanaka ('908) reference teaches a method for providing a sterilant in the vapor phase (col.3, lines 24-58) including the following: creating temperature (figure 1:16) and pressure (the heated gas flowing into inlet 6 in figure 2, is intrinsically pressurized and col.3, lines 26-28) conditions within the vaporizer (figure 2:1), admitting the liquid sterilant to be vaporized (figure 2:20), passing the sterilant through a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9), then passing the sterilant through a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) and passing the

Art Unit: 1797

sterilant out of the vaporizer (figure 1:13). Further, the cross-sectional area of the flow restriction (figure 2, 1, the unlabeled space immediately above the entrance point to 10 has a cross-sectional area) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation such that the Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing. The residence time is based on the desired mixing of the gases. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka ('908) circuitous path and the flow restrictor in order to achieve the desired mixing time. Regarding the disclosed percentage removal of the non-vaporizable components, the Hatanaka ('908) reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

With respect to claims 13 and 17, the Hatanaka ('908) reference fails to teach applying the vapor phase sterilant to a sterilization chamber. The Hatanaka ('255) reference discloses applying the vapor phase sterilant to a sterilization chamber (figure 4:1 and 29). Thus, it would have been obvious to one having ordinary skill in the art to at

the time the invention was made to modify the method of Hatanaka ('908) reference to include a sterilization chamber as taught by the Hatanaka ('255) in order to sterilize packing articles independently of their forms with minimum consumption of hydrogen peroxide (col.1, lines 55-59).

With respect to claim 18, the Hatanaka ('908) reference teaches using any means to remove non-vaporizable components, such as the droplet splash removing apparatus, (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. It would have been obvious to one having ordinary skill in the art to remove any impurities or non-vaporized components from the sterilant vapor prior to injection into a sterilizer in order to ensure the purity of the sterilizing vapor and decrease the risk of contamination to items being sterilized.

Remarks

11. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/02/2007 has been entered.

12. Applicant is advised that he may request to reinstatement of the appeal, or may wish to continue prosecution before the examiner.

Response to Arguments

13. Applicant's arguments filed on 06/07/2007 have been fully considered but they are not persuasive.

Applicant argues that, "Hatanaka et al. does not describe or teach operation below atmospheric pressure." Claims 1 to 3 and 6 are apparatus claims and the Hatanaka reference teaches such features. Then the Hatanaka device is capable of operating at a pressure below atmospheric pressure.

On page 8 of the Remarks section, applicant argues that, "Hatanaka et al. fails to teach operation below atmospheric pressure and fails to teach a flow restriction." The examiner disagrees. As explained above, Claims 1 to 3 and 6 are apparatus claims and the Hatanaka reference teaches such features. The Hatanaka device is capable of operating at a pressure below atmospheric pressure. In addition, with respect to the flow restriction feature, the Hatanaka vaporizer includes a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13).

On page 8 of the Remarks section, applicant argues that, "The Hatanaka and Cummings processes operate under fundamentally different conditions. Cummings injects liquid sterilant into a vacuum with no carrier gas whereas Hatanaka injects sterilant into a flowing carrier gas." The examiner disagrees with the characterization of combining the Hatanaka and the Cummings references. Clearly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka ('908) reference since such a path results in a gas having a uniform

density for improved surface sterilization (col.4, lines 39-40) and not having entrained liquid droplets which would adversely affect the sterilization process (col.4, lines 9-13).

On bottom of page 8 into top of page 9 of the Remarks section, applicant argues that, "Cummings et al. shows a block diagram of two chambers with a valved passage therebetween and the examiner attempts to describe flow restriction status to the passage." The examiner disagrees. Although the Cummings reference appears to show a block diagram, it seems clear that Cummings intends to show two chambers separated by a passage and that passage has a diameter smaller than either chamber. If Cummings had intended only a block diagram, then two blocks separated by an arrow indicating flow direction would have been sufficient. In any event, examiner stresses that the modification of Cummings with the vaporizer of Hatanaka provides the circuitous path and the flow restriction. On page 9 of the Remarks section, applicant argues that, "One of ordinary skill in the art reading this reference would seek to have this flow be as fast and unimpeded as possible." The examiner disagrees since the Cummings reference intention in having a flow restriction between the two chambers is to achieve a certain temperature, pressure and concentration of the sterilant prior to admitting it into the second chamber. Impeding the flow is necessary for the operation of the Cummings reference.

On page 9 of the Remarks section, applicant argues that, "Claim 9 contains the limitation of admitting no carrier gas into the vaporizer. Both of these Hatanaka references rely upon a carrier gas. Accordingly, they fail to teach the claim invention." The examiner points out that claim 9 is rejected over Cummings in view of Hatanaka.

The Cummings reference removes any air originally present within the vaporizer and instead only injects hydrogen peroxide solution into the vaporizer. This feature corresponds to "admitting no carrier gas into the vaporizer".

Applicant's arguments with respect to the Liebold reference have been fully considered. Examiner has dropped the rejections over the Liebold reference and those arguments will not be addressed further here.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.


15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/M. R. C./

/Jill Warden/

Supervisory Patent Examiner, Art Unit 1797

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	09/728,973	NGUYEN ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1797	